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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,406	02/15/2002	Jeffrey L. Browning	BGNB191CPUSDV	4141
959	7590	08/23/2006	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			O'HARA, EILEEN B	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 08/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,406	BROWNING ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54, 57-60, 66, 68-77, 79-84 and 86-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54, 57-60, 66, 68-77, 79-84 and 86-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/9/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1646

DETAILED ACTION

Change of Art Unit and Examiner

1. The Examiner and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1646**.

Claims Status

2. Claims 54, 57-60, 66, 68-77, 79-84 and 86-90 are pending in the instant application. Claims 54, 59, 68-71, 73-77, 79-84, 86 and 87 have been amended, claims 55, 62, 63, 78 and 85 have been canceled and claims 88-90 have been added as requested by Applicant in the Paper filed June 9, 2006.

All claims are currently under examination.

Withdrawn Objections and Rejections

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response or by further consideration and withdrawn.

Information Disclosure Statement

4. On page 19 of the response, Applicant note that they have not received an indication that the references described in the IDS filed with the application on Feb. 15, 2002 have been considered. Although the transmittal letter indicates that an IDS was filed on Feb. 15, 2002, examination of the papers filed on that date indicate that there was no IDS filed in the application on that date.

Priority

5. Applicant is reminded of the following requirement:

In a continuation or divisional application (other than a continued prosecution application filed under 37 CFR 1.53(d)), the first sentence of the specification or application data sheet (37 CFR 1.76) should include a reference to the prior application(s) from which benefit of priority is claimed, and also the status. See 37 CFR 1.78. The first sentence should read -- This is a divisional of U.S.S.N. 09/000,166, filed June 8, 1998, now U.S. patent number 6,403,087, which is the national stage entry of PCT/US96/12010, filing date July 19, 1996, which is a continuation-in-part of U.S.S.N. 08/505,606, filed on July 21, 1995, now U.S. patent number 5,925,351. --

Page 2 of the preliminary amendment filed February 15, 2002 has the priority statement in the first sentence, but it is not complete.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

Art Unit: 1646

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6.1 Claims 54, 57-60, 66, 68-77, 79-84 and 86-90 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,925,351, claims 1-14 of U.S. Patent No. 6,403,087 and claims 1-11 of U.S. Patent No. 6,669,941. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are all drawn to methods of treating autoimmune disorders by administering an agent that blocks LT- β -R signaling.

6.2 Claims 54, 57-60, 66, 68-77, 79-84 and 86-90 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55-62 and 64 of copending Application No. 10/003,211. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are all drawn to methods of treating autoimmune disorders by administering an agent that blocks LT- β -R signaling.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1646

7. Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 66 requires that the soluble LT- β -R is administered in an amount sufficient to coat LT- β *receptor* positive cells, but the soluble receptor would not bind to the full-length receptor present on the cell surface. This rejection would be overcome by replacing “receptor positive cells” with “ligand positive cells” as disclosed in the specification at paragraph 0188.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 81- 84, 86 and 87 are indefinite because claim 1 recites “consisting essentially of an amino acid sequence, and the phrase “consisting essentially of” refers to compositions, so it is not clear how it pertains to a protein.

Pertinent Art

9. The art considered pertinent to the present application is Gommerman et al., Nature Rev. Immunology, Vol.3, No. 8, August 2003, pages 642-655, which teaches that inhibition of LT- β -R signaling can inhibit autoimmune diseases in animal models including arthritis, inflammatory bowel disease, multiple sclerosis, myasthenia gravis, diabetes, colitis and psoriasis (Table 2 and page 651). This reference is cited as providing support for the claims.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.


The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner


EILEEN B. O'HARA
PRIMARY EXAMINER